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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)	
	09/756,551	MORROW ET AL.	
	Examiner	Art Unit	
	Joseph T Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *49-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *49-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a continuation of 09/376,184, filed August 17, 1999, now abandoned, which is a continuation of 08/987,867, filed December 9, 1997, now patent number 6,063,384, which is a continuation of 08/389,459, filed February 15, 1995, now patent number 5,817,512, which is a continuation of 08/087,009, filed July 1, 1993, now abandoned.

Election/Restriction

Applicant's election of Group II and the species of IL-6 in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon review of the restriction requirement it is found that the relationship of the claims was incorrectly set forth. Specifically, claim 49 is a linking claim encompassing both *in vivo* and *ex vivo* methods of expression. Upon reconsideration of the pending claims it is found that examination of both groups I and II would not constitute an undue burden. Therefore, the restriction requirement is withdrawn.

Additionally, while each of the expressed products specifically set forth in the claims are technically genes, the products are not related species of each other. However, because the methods are drawn to simply expressing a gene and the various genes specifically set forth are not novel to this disclosure and were well known in the prior art, upon reconsideration it is found

that examination of all the species not constitute an undue burden. Moreover, because the specific genes are not essential to the inventive concept of the claimed invention examination of the all the gene products would allow for effective coverage of the invention presented in the application. Therefore, the election of species is withdrawn.

Claims 49-63 are pending and currently under examination as they are drawn to a method of expressing a foreign gene in a cell both *in vivo* and *ex vivo*.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). Upon review of the disclosure it is found that figures 23 B and C contain amino acid sequences which are not identified by SEQ ID NOs neither in the figure itself nor the description of the figure (page 6). Further, it does not appear that the sequences are identified and provided in the sequence listing (pages 54-73).

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 49 is unclear in their recitation of 'foreign protein' because the metes and bounds are not clear in what constitutes foreign. The specification recites the use of a foreign protein and gives several examples (page 10; lines 6-26) for producing an immune response, however, the specification does not clearly define what is meant by foreign. The term foreign is relative to the intended use and practice of the instantly claimed method. It is unclear if the protein is foreign to the whole subject or to just the cell into which it is introduced. For example, claim 53 recites several cell types found in mammals, however, claims 57-60 recite genes encompassing gene products which are also found in mammals. It is unclear if using the poliovirus vector in humans to express a human protein would infringe on the instantly pending claims. Additionally, it is unclear what is encompassed by the recitation of "an effective amount of the composition" because what is being effected is not specifically set forth. It is unclear if the effective amount is in reference to an amount associated with a specific affect which is a consequence of a specific gene product or if refers to only providing expression in a cell. Further, it is unclear because the amount of expression to be effected is not clearly set forth.

Claim 58 is vague and unclear in the recitation of 'a factor'. Upon review of the specification a specific definition of this term can not be found. Since the specification does not specifically define the term and there is no general art accepted understanding of the term, it is unclear what type of genes are encompassed by this recitation. Indicating support for this term in the specification and more clearly setting forth what is encompassed by the term would obviate the basis of the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-57, 61 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,063,384. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. In this case, both sets of claims encompass methods of expressing any protein comprising practicing the same method steps with effectively the same materials. It is noted that the claims of '384 set forth in the preamble that the method is for stimulating an immune response however in both sets of claims the same poliovirus vector is used and in dependent claims the same specific gene products are expressed. For example, '384 recites that HIV proteins are expressed (claim 4) and in the instant application claim 62 also recites HIV genes are expressed. Tumor and cancer associated products are also specifically set forth (claims 7-8 in '384 and claim 61 of the instant application). Further, the methods encompass the same routes of administration and indicate the same target cell for expression of

the gene products, for example cutaneous and muscle cells (claim 53) and IM injections (claim 3). While the claims of the instant application do not recite the intended result of practicing the method, because the method steps are the same and result in the expression of the same products in a cell in an individual, the resulting affect must be the same.

Claims 49-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 5,817,512. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. In this case, the claims of '512 encompass recombinant polio virus polynucleotide sequences and methods of making. More specifically, the recombinant polynucleotide sequences incorporate a foreign nucleotide and encode a foreign protein (claims 1 and 2). In particular, the P1 protein from the polio virus is lacking from the vector (claim 3). Moreover, the specific proteins expressed are viral HIV proteins (for example claim 12), tumor antigens (for example claim 10), B and T cell linear epitopes and cytokines (for example claim 15). The instant claims are obvious over the products and methods of making

said products because the only intended use of the recombinant poliovirus vectors set forth in the specification is for the expression of heterologous gene products contained within the poliovirus vector.

Conclusion

No claim is allowed. The claims are free of the art of record, however they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

Joe Woitach

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